

### REMARKS

Based on the election with traversal presented below, Applicants have added to claims 1, 8 15 and 17 the limitations directed to the elected species. Accordingly, claims 2-4 and 12 are cancelled and the dependencies of claims 13-15 are amended. No new matter is added. Entry is believed to be proper and respectfully requested.

### APPLICANTS ELECTION WITH TRAVERSE

#### The Examiner's Restriction Requirement

In the Office Action dated September 17, 2001, the Examiner requires election of species alleged to be patentably distinct, within two groups. According to the Examiner the species are:

- A) Primary Challenge
  - i) Biological
  - ii) Chemical
  - iii) Physical
  
- B) Secondary Challenge
  - i) Biological
  - ii) Chemical
  - iii) Physical

The Examiner contends that each type of challenge has unique physical, chemical, and biological properties which give each species unique enablement and search requirements.

#### Applicant's Election with Traverse

Applicants hereby elect to prosecute the chemical (ii) subject matter within the primary challenge (A) and the physical (iii) subject matter within the secondary challenge (B). Claims that read on the elected species are claims 1, 5-11 and 13-20, as amended in the present response.

However, Applicants respectfully traverse the requirement, as the Examiner has not demonstrated that the restriction is proper.

Applicants submit that the Examiner fails to provide any reason for alleging that the species are distinct. MPEP §816 states that "[t]he particular reasons relied on by the Examiner for holding that the inventions as claimed are either independent or distinct, should be concisely stated. A mere statement of conclusion is inadequate. The reason upon which the conclusion is based should be given." Here, the Examiner stated only that "[e]ach type of challenge has unique physical, chemical, and biological properties which give each species unique enablement and search requirements". This is merely a statement of conclusion, inadequate to support a restriction requirement. Applicants submit, on this basis alone, the present restriction requirement is improper and should be withdrawn.

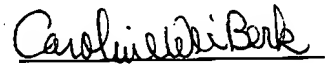
Further, This failure to provide reasons for the restriction requirement makes it impossible for Applicants to present a meaningful traversal in this response.

Moreover, Applicants submit that the Examiner has not shown a serious burden if the restriction is not required. MPEP §808.02 states that "the Examiner, in order to establish reasons for insisting upon restriction, must share by appropriate explanation one of the following criteria: (1) separate classification thereof; (2) a separate status in the art when they are classified together; or (3) a different field of search." The Examiner points to none of these reasons for insisting upon restriction. Applicants point out that all the claims are related in so far as they all are directed to a test method which applies a primary challenge to a responsive system, and uses a secondary challenge to enhance and/or prolong the effects of the primary challenge so that the primary challenge can be better studied. The exemplary primary and secondary challenges merely represent alternative embodiments. Accordingly, the patentability search would be coextensive. The Examiner has no clear indication that the various embodiments would be put into separate classifications or require a different field of search. Applicants submit that the restriction requirement is also improper on this basis.

#### Conclusion

Based on the foregoing, Applicants respectfully submit that restriction in the present case is improper and request that the restriction requirement be withdrawn. However, if the restriction is made final, Applicants choose to prosecute claims 1, 5-11 and 13-20, as amended in the present response.

Respectfully submitted,  
For: Tcppe et al.

  
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5

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims

Please cancel claims 2-4 and 12 without prejudice.

Please amend the following claims:

1. (Amended) A method comprising the steps of:
  - a) subjecting a test site of a responsive system to a primary challenge;
  - b) subjecting the test site to a secondary challenge, wherein the secondary challenge differs from the primary challenge and wherein the secondary challenge is designed to enhance, and/or prolong a response of the responsive system to the primary challenge; and
  - c) d) assessing the response;  
wherein the primary challenge is a chemical challenge and the secondary challenge is a physical challenge.
8. (Amended) A study comprising the steps of:
  - a) applying a primary challenge to a test site of a responsive system; applying a secondary challenge to the test site, wherein the secondary challenge differs from the primary challenge and wherein the secondary challenge is designed to enhance and/or prolong a response of the responsive system to the primary challenge, wherein the primary challenge is a chemical challenge and the secondary challenge is a physical challenge; and
  - b) creating one or more controls selected from the group consisting of negative controls, primary controls, secondary controls, positive controls, and mixtures thereof.
13. (Amended) [A] The method according to Claim [12] 1 wherein the secondary challenge is tape-stripping.
14. (Amended) The method according to Claim [12] 1 wherein the primary challenge comprises more than one component and/or step.
15. (Amended) The method according to Claim [12] 1 wherein the chemical [and/or biological] challenge is applied to the test site via a patch.
17. (Amended) The method according to Claim 16 wherein the chemical [and/or biological] challenge comprises applying stool and/or stool analog.